AWARD NUMBER: W81XWH-14-2-0160

TITLE: Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health, and Physical Performance

PRINCIPAL INVESTIGATOR: Oscar E. Suman, PhD

CONTRACTING ORGANIZTION: The University of Texas Medical Branch at Galveston
Galveston, TX 77555

REPORT DATE: October 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health, and Physical Performance

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W81XWH-14-2-0160

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
The University of Texas Medical Branch at Galveston
301 University Boulevard
Galveston, TX 77555-5302

8. PERFORMING ORGANIZATION REPORT NUMBER

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U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Prolonged inactivity accompanying stays in the burn intensive care unit (BICU) and hospital worsen muscle loss/weakness and lengthen hospitalization. We hypothesize that a personalized, structured, and quantifiable exercise program (MP10) will improve these variables over standard-of-care (SOC), as exercise has well-documented effects on maintaining/improving muscle strength, which should shorten hospitalization. Thus, we will characterize: (Aim 1) what is SOC throughout hospital stay across the US and (Aim 2) outcomes in burn in-patients. Over 4 years, we will enroll 96 patients (24 per site; MP10 n=64 and SOC n=32) aged 18-60 years with ≥30% TBSA burns. MP10 will begin ~4-5 days after the first surgery after admit (or when the burn surgeon deems mobilization safe) and continue for the entire BICU and hospital stay. MP10 will take place on weekdays in the morning and afternoon. In the morning, patients will participate in a 10-minute leg-crank ergometry session (Monark leg ergometer), starting with a load (watts) eliciting a 3-5 rating on the Borg Rated Perceived Exertion (RPE) scale. The number of revolutions in 10 minutes and minute-by-minute muscle and respiratory effort RPE will be noted. In the afternoon, patients will participate in a 10-minute arm crank ergometry session, which will be done similarly to lower body exercise. Endpoints are lean body mass, cardiopulmonary and muscle endurance, length of BICU, ventilator and hospital stay, and Quality of Life. Within- and between-group comparisons will be performed. A successful MP10 can be a platform for future rehabilitation programs in burns or trauma.

15. SUBJECT TERMS

Nothing listed

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	26	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. INTRODUCTION:

The title of this project is "Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health and Physical Performance". It has four sites: UTMB-Galveston, TX; AISR-San Antonio, TX; UTSW-Dallas, TX; UC-Davis. The prolonged inactivity that occurs in the burn intensive care unit (BICU) and hospital, results in worsening of muscle loss, muscle weakness, and in increased BICU and hospital stay. We need to reduce this time to speed up resuming normal physical activities, returning to work or to professional duties. To this end, we have two aims: **Aim 1**: to characterize, via a survey(s) the Standard of Care of in-patient care (BICUs, on ventilator, step down from BICU) across the U.S. **Aim 2**: to assess the efficacy of a personalized, structured, and quantifiable exercise program (MP10) implemented typically 4 to 5 days after the first surgical operation after admit (or when burn surgeon deems mobilization to be safe), and during the entire BICU, on ventilator and in-hospital stay in burned individuals.

2. KEYWORDS:

Exercise, burns, standard of care, MP10, early exercise, lean mass, muscle strength, 6 minute walk

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals and objectives of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Milestones:
Aim 1: to characterize, via a survey(s) the Standard of Care of in-patient care (BICUs, on ventilator, step down from BICU) at the 4 sites (UTMB-Galveston, USAISR, UTSW-Dallas, UC Davis)
Due: Y3 Report 11-Oct-2017 which covers SEP 15, 2016 to SEP 14, 2017.
Surveys were sent to all sites and results were returned from all sites. The results for AIM 1 were presented at the International Society for Burn Injuries (AUG 29-SEP4, 2016) in Miami, FL. The manuscript summarizing and discussing the results has been written. We submitted to the *Burns* journal. Unfortunately it was rejected. We are now revising the manuscript and will submit by the end of October 2017. We have submitted this manuscript to the Journal of Burn Care and Research. Submitted October 20, 2017.

Aim 2: to assess the efficacy of a personalized, structured, and quantifiable exercise program (MP10) implemented typically 4 to 5 days after the first surgical operation after admit (or when burn surgeons deems mobilization to be safe) and during the entire BICU, on ventilator and in-hospital stay in burn individuals. UTMB, UC-Davis and UTSW are enrolling patients. The USAISR is currently in the process of obtaining their IRB approval. For UTMB, a total of 46 subjects have been enrolled, which more than completes the 24 that were proposed for this site. We have requested permission to increase the number of subjects from 24 to an additional 72 for a total of 96. We have obtained verbal permission from Dr. Lai. We submitted official request to the UTMB IRB on October 12, 2016.

Due: Final Report 12-Dec-2018 Completion Date: 14-Sep-2018

Year 2 Key Milestones: Get site ready for study (completed); develop individual data forms and survey (completed); obtain IRB and HPRO approvals (completed for UTMB, UTSW, USAISR and UC-Davis); register with clinicaltrials.gov (completed). **At this date, all sites have IRB approval and HRPO approval.**

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1) Major activities
For this Year 3 period of September 15, 2016 to September 14, 2017,
We focused on recruiting additional patients at UTMB as the lead site. Then we focused on each site obtaining HRPO and progressing with Aim 2, (in-patient exercise).

More specifically: **from 15-SEP-2016 to 14-DEC-2016**, UTMB received IRB approval to conduct study from 06-Oct-2016 until 16-Sep-2017 (IRB 14-0432).

On October 13, 2016, the Annual Progress Report for Year 2 was submitted to Dr. Lai. We reported in this annual report that the two most salient "to be completed" business were: obtain IRB approval for UTMB to increase enrollment from 24 to 96. Since then, we have obtained approval to increase our enrollment numbers at the UTMB/SHC-Galveston site to 96 subjects. The second business point was to later on discuss to potentially re-budget to reallocate funds for UTMB mainly for staff, and for UC-Davis for DEXA and transport billing. No additional funds were requested, but involved only reallocation of funds. We have since contacted Dr. Kowalske at UTSW site and Dr. Kowalske approved transferring of funds from her site to UCD/SHC-NCA due to lower than expected enrollment at UTSW.

On November 9, 2016, Kara Visser, from the CTR USARMY MEDCOM USAMRMC sent email that read: "You have the go-ahead to enroll patients! Please continue all research-related activities." This was for the Galveston site and included the increase in number of subjects.

On November 18, KIMBERLY L. ODAM, MS, CIP, Deputy Director of the Human Research Protection Office and Office of Research Protections, sent an email to Dr. Suman where it states that

SUBJECT: Continuing Review Acceptance for the Protocol, "Randomized, Controlled, Multicenter Study of the Effect of In-Patient Exercise Training on Length of Hospitalization, Mental Health, and Physical Performance in Burned Patients," Submitted by Oscar E. Suman, PhD, University of Texas Medical Branch, Galveston, Texas, in Support of the Proposal, "Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health, and Physical Performance," Proposal Log Number 13214039, Award Number W81XWH-14-2-0160, HRPO Log Number A-18468.a

1. The US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the subject protocol on 29 January 2015.

2. The HRPO received a continuing review report for the subject protocol on 19 October 2016. The University of Texas Medical Branch Institutional Review Board (IRB) approved continuation of the protocol on 6 October 2016; this approval will expire on 16 September 2017.

Thus, HRPO approval for UTMB site is from 06-OCT-2016 until 16-SEP-2017.

UTMB/SHC-GAL intends on continuing to screen and enroll patients. No Changes/Problems are noted at this time. No actual problems or delays or anticipated problems/issues noted at this time for this site.

During this period at UTMB, a total of 24 patients had been enrolled and completed the MP10+SOC or SOC protocol as applicable. This met our recruitment goal. On October 6, we received IRB approval for assessment procedures, however, since we had met our enrollment goals, we requested to increase the number of subjects from 24 to 96 for UTMB. An amendment was sent to IRB on October 12, 2016. Approval is pending at this moment. Other accomplishments are the presentation of AIM ONE results at the International Society for Burn Injuries AUG 29 to SEP 4, 2016 in Miami, FL. From this presentation, a manuscript has been prepared. We anticipate submitting a manuscript for peer review before November 2017.

For this Year 3 period of December 15, 2016 to March 14, 2017, we obtained UTMB IRB approval from 06-Oct-2016 until 16-Sep-2017 (IRB 14-0432).

HRPO approval for UTMB site is from 06-OCT-2016 until 16-SEP-2017

UTMB/SHC-GAL continued to screen and enroll patients. No Changes/Problems were noted at this time. No actual problems or delays or anticipated problems/issues noted at this time for this site.

For Year 3, Q3; Period of March 15, 2017 to June 14, 2017 we obtained UTMB IRB approval is from 06-Oct-2016 until 16-Sep-2017 (IRB 14-0432). HRPO approval for UTMB site is from 06-OCT-2016 until 16-SEP-2017. UTMB/SHC-GAL continued to screen and enroll patients. No Changes/Problems were noted at this time. No actual problems or delays or anticipated problems/issues noted at this time for this site. Ten patients met inclusion criteria. Three rejected participation; and seven accepted to participate.

Currently as of October 20, 2017, we have the following:

Total admitted sept15,2016-Sept14,2017	79	Exclusion criteria	50			
			Age	36		
			TBSA	10		
			Electrical	4		
			Mental retardation	0		
		Inclusion criteria	29			
			Reject	9		
			Accept	20	MP10+SOC	15
					SOC	5

To date we have enrolled 46 patients (signed consent form). Of those, 30 are in the MP10 group and 16 are SOC

Below is a table with number of patients enrolled in the three years of the study

Site	Pts enrolled
UTMB/SHC-Galveston	46
UC-Davis/SHC-Sacramento	7-8
UTSW	1-3
USAISR	1

We also have UTMB IRB and HRPO approval as stated in this email.
SUBJECT: Continuing Review Acceptance for the Protocol, "Randomized, Controlled, Multicenter Study of the Effect of In-Patient Exercise Training on Length of Hospitalization, Mental Health, and Physical Performance in Burned Patients," Submitted by Oscar E. Suman, PhD, University of Texas Medical Branch, Galveston, Texas, in Support of the Proposal, "Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health, and Physical Performance," Proposal Log Number 13214039, Award Number W81XWH-14-2-0160, HRPO Log Number A-18468.a

1. The U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the subject protocol on 29 January 2015.

2. The HRPO received a continuing review report for the subject protocol on 18 September 2017. **The University of Texas Medical Branch Institutional Review Board (IRB) approved continuation of the protocol on 13 September 2017; this approval will expire on 8 September 2018**.

3. **The submitted continuing review report and supporting documentation have been reviewed by the HRPO and found to be in compliance with Federal, DOD, and U.S. Army human subjects protection requirements. The report and supporting documents are accepted.**

What opportunities for training and professional development has the project provided?

"Nothing to report"

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

"Nothing to Report." However, quarterly, we do get together with UTSW and USAISR key investigators of this project and discuss progress and issues. The next meeting will take place on November 17, 2017 at the University of Texas-Houston Health Science Center, and we will attend. In addition, we will try to have a 4-site (all sites) meeting at the next American Burn Association in Chicago in April 2018 to discuss progress and obstacles and plans for the final fourth year of grant. Finally, the project PI, Dr. Suman, gave a presentation on the timing of exercise at the International Society for Burn Injuries (AUG 29 to SEP 4, 2016) in Miami, FL. The MP10 methodology was presented and well received, as it highlighted the objective nature of the exercise prescription and significant outcome measures. Dr. Suman intends to give a presentation of preliminary findings of MP10 at the Mexican Burn Association meeting in April 2018, and final MP10 findings at the American Burn Association meeting in Las Vegas in March/April 2019.

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

For Aim 1. We will prepare and submit manuscript on the results of the 6-site survey on Exercise in the ICU. We have submitted to the Journal of Burn Care and Research this manuscript. Submitted October 20, 2017.

For Aim 2, we will continue to enroll, especially for UCD/SHC-NCA. For UTSW and USAISR, we do not anticipate enrollment to be significant or at all.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

"Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.
"Nothing to Report."

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

"Nothing to Report."

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

UTMB has enrolled 46 subjects, which is more than the proposed total number of 24 for this site. We requested and obtained verbal permission to increase total number of subjects from 24 to 96 (thus enroll 72 more patients during years 3 and 4). This request was approved by UTMB's IRB.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

At USAISR there have been numerous changes in personnel. The most noticeable one is that Sandra M. Escolas, PhD left San Antonio to become Director of the US Army Medical Research Unit-West in McChord, WA. Dr. Escolas was recently transferred back to Texas, so she will remain involved, but we will have to communicate via phone, email, etc., and not in person. We may be able to meet during conferences now that she is back in Texas. Also the PI (Dr. Suman) may travel there to discuss key issues related to psychosocial assessments once enrollment has been finalized.

USAISR had not been able to hire a grants coordinator that could focus on the MP10 project. For a long time, Mr. Reginald Richards had been vital and key to keeping progress going, however, he has retired. A new PI, Dr. Julie Rizzo, and another coordinator, Sonya Charo-Griego came on board. They have been able to devote much effort to MP10, and they have obtained IRB approval. However, enrollment remains elusive.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

There is nothing to report for UTMB/SHC-GAL. However, for UCD/SHC-NCA, we have increased the amount allotted to this site, so they can complete obtaining DEXA. The costs are new and involve the DEXA itself and transport costs. We have decreased the amount of money allotted to UTSW based on enrollment progress (n=1 for UTSW) vs (n=7 for UC-Davis). This was discussed with the program officer, Dr. Lai. Finally, the potential continued shortage of personnel at USAISR specific to the MP10 project may have affected and if continued, will eventually affect expenditures. If continued, we will be seeking a budget amendment to increase funds for UTMB, particularly for personnel. We will do this as soon as this Y3 annual report is approved.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

UTMB has enrolled 46 subjects, which is more than the proposed total number for this site. We requested and obtained verbal permission to increase total number of subjects from 24 to 96 (thus enroll 72 more patients during years 3 and 4). We have submitted this request to our IRB and it was approved. The methods and outcomes measures have not changed. To date we have enrolled 46 patients at UTMB.

Significant changes in use or care of vertebrate animals.

Not applicable.

Significant changes in use of biohazards and/or select agents

"Nothing to Report."

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

Journal publications.
"Nothing to Report."

Books or other non-periodical, one-time publications.

"Nothing to Report."

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if*

1. Oral presentation at the International Society for Burn Injuries (AUG 29 to SEP 4, 2016) in Miami, FL. The results of the Survey on Exercise Practice in the ICUs of the 4 sites were presented by Ingrid Parry, MS, PT. She is the study coordinator and PT at UC-Davis/SHC-NCA. She and the PI have led in the preparation of the manuscript. The Survey results were the combined efforts of Ingrid Parry and Jennifer Kemp (OT from UTMB/SHC-GAL).

2. Finally, the project PI, Dr. Suman, gave a presentation on the timing of exercise at the International Society for Burn Injuries (AUG 29 to SEP 4, 2016) in Miami, FL. The MP10 methodology was presented and well received, as it highlighted the objective nature of the exercise prescription and significant outcome measures.

Website(s) or other Internet site(s)
List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Name: *Oscar Suman*
Project Role: *Project Director*
No change.

Name: *Michael Serghiou*
Project Role: *Consultant*
No change.

Name: *Jennifer Kemp*
Project Role: *Consultant*
No change.

Name: *Ronald Mlcak*
Project Role: *Consultant*
No change.

Name: *Angela Agudelo*
Project Role: *Clinical Research Coordinator*
Researcher Identifier (e.g. ORCID ID): *not applicable*
Nearest person month worked: *2 calendar months*
Contribution to Project: *She has been the hands-on physical therapist and exercise trainer in the ICU.*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

See Attachment "Changes in Active Other Support"

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Organization: University of California – Davis
Location: 1850 Research Park Dr. Ste. 300, Davis, CA 95618-6153
Contribution to the Project: Collaboration

Organization: The University of Texas Southwestern Medical Center at Dallas
Location: 5323 Harry Hines Blvd., Dallas, TX 75390-9105
Contribution to the Project: Collaboration

Organization: US Army Institute of Surgical Research
Location: 3698 Chambers Pass, Ft. Sam Houston, TX 78234-6315
Contribution to the Project: Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS: I

9. APPENDICES:

See Attachment 1: Changes to Active Other Support

CHANGES IN ACTIVE OTHER SUPPORT

Suman, Oscar E.
#71006, Shriners Hospitals for Children (PI: Suman) ended 12/31/16
#71009, Shriners Hospitals for Children (PI: Suman) ended 12/31/16
2014-667 Suman MPI Pilot (PI: Suman) ended 11/30/16
#71008, Shriners Hospitals for Children (PI: Herndon) ended 12/31/16
90DP0043-02-00 (PI: Herndon) ended 9/29/17
#84080, Shriners Hospitals for Children (PI: Herndon) renewed 1/1/17
90DPBU0003-01-00 NIDILRR (PI: Herndon) renewed 9/30/17

W81 XWH-14-2-0160 (Suman) 09/15/14-09/14/18 1.56 cal mths
Dept of Defense
"Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health and Physical Performance"

Goal: To obtain a successful, quantifiable exercise program (MP10) which can be a platform for future rehabilitation programs in burns or trauma.

Aims: 1) To characterize what is Standard of Care throughout hospital stay across the US. 2) To characterize outcomes in burn inpatients.

Role: Principal Investigator
Contact: Doug Medcalf, 301-619-2394, douglas.a.medcalf.civ@mail.mil
Overlap: This is the grant for which the progress report is being submitted.

2 R01 HD049471-10 (Suman) 02/01/15-01/31/20 2.16 cal mths
National Institutes of Health
"Oxandrolone and Exercise: A Potent Therapy in the Rehabilitation from Burns"

Goal: To identify evidence-based therapeutic interventions that are clinically effective in the rehabilitation and recovery of severely burned children.

Aims: 1) To determine the physiological therapeutic efficacy of exercise training/rehabilitation plus oxandrolone relative to exercise alone; 2) To determine the biochemical consequences of combined exercise training/rehabilitation and oxandrolone relative to those of exercise alone.

Role: Principal Investigator
Contact: Valerie Maholmes, valerie.maholmes@nih.gov, 301-496-1514, 6100 Executive Blvd, Rockville, MD 20852
Overlap: None

*****End Date Extended*****
W81XWH-09-2-0194 (Wolf/Suman) 09/30/09-10/29/17 0.24 cal mths
American Burn Association
"Community-Based Exercise Rehabilitation in Severely Burned Adults"

Goal: To assess the efficacy of implementing a 12-week structured and supervised community-based exercise program (COMBEX) started at hospital discharge.

Aims: The central hypothesis of this proposal is that exercise-induced physical and psychosocial benefits obtained during a supervised and structured community-based exercise program in severely burned adults will improve physical function, and quality of life relative to the Standard of Care.

Role: Principal Investigator
Contact: American Burn Association, 312-642-9260
Overlap: None

P50 GM060338-15 (Herndon) 09/15/12-08/31/17 1.92 cal mths
National Institutes of Health
"Mitigation of the Catecholamine Surge in Severely Burned Patients"
This is a program project grant that will study the efficacy, effects and mechanisms of the reduction in post-burn catecholamine surge by the non-selective beta-1 and beta-2 adrenergic antagonist, propranolol, in severely burned children and adults.
Project Title: Project 1: Propranolol Effects, Clinical Outcomes and Quality of Life in the Severely Burned

Goal: This NIH-defined Phase II, intent-to-treat, clinical trial will allow assessment of the effects of propranolol on many organ systems affected by the catecholamine surge, determination of

whether blocking the stress response is beneficial or harmful, determination of the molecular mechanisms, determination of whether a full year of treatment is tolerable to most patients, and establishment of a treatment protocol with high compliance rates for future expansion into multi-center trials

Aims: 1) To determine the effects of long-term propranolol administration on cardiac work as reflected by the product of heart rate and mean arterial blood pressure, and resting energy expenditure as reflected by resting oxygen consumption; 2) To determine the effects of long-term propranolol administration on muscle mass and muscle function, as reflected by lean body mass index and peak strength; 3) To assess changes in key biomarkers of inflammation and infection (C-Reactive Protein and Interleukin-6) in response to the long-term administration of propranolol; 4) To determine if propranolol administration improves psychosocial health (Quality of Life) when assessed one year post burn

Role: Principal Investigator
Contact: Scott D. Somers, PhD, Program Official, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

End date extended*
P50 GM060338-15 (Herndon) 09/15/12-08/31/17 0.96 cal mths
National Institutes of Health
"Mitigation of the Catecholamine Surge in Severely Burned Patients"
Project Title: Core A: Administrative Core

Goal: This NIH-defined Phase II, intent-to-treat, clinical trial will allow assessment of the effects of propranolol on many organ systems affected by the catecholamine surge, determination of whether blocking the stress response is beneficial or harmful, determination of the molecular mechanisms, determination of whether a full year of treatment is tolerable to most patients, and establishment of a treatment protocol with high compliance rates for future expansion into multi-center trials

Aims: To function as the administrative and organizational structure that coordinates the activities of the Research Center and facilitates its scientific mission

Role: Core Director
Contact: Scott D. Somers, PhD, Program Official, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

End date extended*
P50 GM060338-15 (Herndon) 09/15/12-08/31/17 0.24 cal mths
National Institutes of Health
"Mitigation of the Catecholamine Surge in Severely Burned Patients"
Project Title: Core C: Human Subjects Core

Goal: This NIH-defined Phase II, intent-to-treat, clinical trial will allow assessment of the effects of propranolol on many organ systems affected by the catecholamine surge, determination of whether blocking the stress response is beneficial or harmful, determination of the molecular mechanisms, determination of whether a full year of treatment is tolerable to most patients, and establishment of a treatment protocol with high compliance rates for future expansion into multi-center trials

Aims: To enroll patients, gather clinical data and measurements, and oversee the acquisition,

compilation, and dissemination of all clinical and biological data, as well as to collect, catalogue, and distribute patient samples, and to perform basic protein and genetic analyses

Role: Co-Investigator
Contact: Scott D. Somers, PhD, Program Official, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

End date extended*
P50 GM060338-15 (Herndon) 09/15/12-08/31/17 0.24 cal mths
National Institutes of Health
"Mitigation of the Catecholamine Surge in Severely Burned Patients"
Project Title: Project 9: Effects of Propranolol on Hypermetabolism

Goal: This NIH-defined Phase II, intent-to-treat, clinical trial will allow assessment of the effects of propranolol on many organ systems affected by the catecholamine surge, determination of whether blocking the stress response is beneficial or harmful, determination of the molecular mechanisms, determination of whether a full year of treatment is tolerable to most patients, and establishment of a treatment protocol with high compliance rates for future expansion into multi-center trials

Aims: 1) To define the short- and long-term effects of propranolol on a) the development of hepatic steatosis, b) the rate of peripheral lipolysis and systemic FFA availability, and c) very low density lipoprotein-triglyceride (VLDL-TG) kinetics in severely burned patients; 2) To define the short- and long-term effects of propranolol on muscle protein synthesis and breakdown rates, and b) elucidate the mechanisms responsible for the observed propranolol induced alterations in muscle protein metabolism in severely burned patients; 3) To determine the correlations between changes in hepatic steatosis and muscle protein metabolism with changes in body composition and energy expenditure, insulin resistance, and inflammation

Role: Co-Investigator
Contact: Scott D. Somers, PhD, Program Official, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

2 R01 GM056687-14 (Herndon) 08/05/14-04/30/18 0.48 cal mths
National Institutes of Health
"Mechanisms of fenofibrate alone or combined with propranolol in burned patients"

Goal: This long-term clinical trial will advance the understanding of burn-induced tissue-specific signaling pathways, alterations in clinical indices such as insulin resistance, body composition, and scarring, and may
improve clinical outcomes of burn patients, and by extension also improve these in other hypermetabolic and hypercatabolic states.

Aims: Aim 1: will characterize the effects of fenofibrate and propranolol on muscle protein metabolism, regional lipid metabolism, and insulin resistance, after severe burn. Aim 2a: will test the efficacy of these agents on wound closure, wound infection, graft rejection, and scarring (the modified Vancouver and Seattle scar scales). Aim 2b, will determine whether these agents alter wound protein turnover and healing rates by using stable isotope techniques. Aim 2c, will use fibroblasts isolated from skin and scar biopsies to study molecular signaling pathways related to wound healing and scar development. Aim 3: will test the hypothesis that the mechanistic results of SA1 and SA2 are highly associated with improvements in outcomes vital in the acute stage: inflammatory response as reflected by interleukin-6, as well as result in improvements in long term outcomes: lean body mass, resting energy expenditure, cardiac function and quality of life.

Role: Co-Investigator
Contact: Scott D. Somers, PhD, Program Official, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

1 R01 GM112936-01 (Finnerty) 01/15/15-12/31/19 0.60 cal mths
National Institutes of Health
"Effects of Chronic Catecholamine Exposure on Post-burn Scarring"

Goal: Understanding the mechanisms underlying aberrant wound healing and scarring, and their reversal by propranolol, will lay the foundation to develop additional anti-scarring therapies for the severely burned.

Aims: Aim 1. Determine the effects of chronic catecholamine exposure and β-blockade on wound healing and hypertrophic scars. Aim 2. Quantitate the effects of β-blockade on scar composition. Aim 3. Determine the effects of β-blockade on β-AR expression, activity, and binding partners of dermal fibroblasts.

Role: Co-Investigator
Contact: Tseng, Hung H., 301-496-0810, tsengh@mail.nih.gov
Overlap: None

W81XWH-15-1-0143 (Branski) 07/01/15-06/30/19 0.48 cal mths
Dept of Defense
"Growth Hormone Therapy for Muscle Regeneration in Severely Burned Patients"

Goal: To determine whether restoration of depleted GH levels post-burn will lead to prevention of lean body mass loss and bone mineral content, improve rehabilitation, and accelerate reintegration of severely burned patients.

Aims: To determine the effects of recombinant human growth hormone (rhGH) supplementation on body composition, such as lean body mass loss and bone mineral content, and to assess if rehabilitation and subsequent reintegration of severely burned patients into society can be

accelerated.

Role: Co-Investigator
Contact: Primary contact: Dr. Nicole Enman, Science Officer, CDMRP, Phone: (301) 619-7040, Email: nicole.m.enman.ctr@mail.mil
Overlap: None

84080 (Herndon) 01/01/17-12/31/20 0.60 cal mths
Shriners Hospitals for Children
"Special Shared Facility: Clinical Research and Computer Research Support"

Goal: To provide clinical research education and support to funded, unfunded, and pilot burn research projects at SHC Galveston.

Aims: 1) To provide an organizational and functional structure to all clinical research performed including scientific, financial, and administrative support; 2) To direct daily activities and evaluate all shared activities of the SSF; 3) To provide the supportive function of offering Information Systems Services to all research staff in the building consistent of networking and desktop hardware, software, and technical support; 4) To maintain a repository of human samples and research data; 5) To provide education and oversight of all clinical research performed with SHC Galveston patients through the monitoring of all clinical trials using the OnCore software program.

Role: Co-Investigator
Contact: Carole Miller, 815 Market St, Galveston, TX 77550, 409-770-6728 , cmiller@utmb.edu
Overlap: None

90DPBU0003-01-00 (Herndon) 09/30/17-09/29/22 0.96 cal mths
National Institute on Disability, Independent Living, and
"Effects of anabolic steroids and blockade of chronic catecholamine mediated stress on psychosocial, growth, scar, and physiologic outcomes after massive burn injury"

Goal: Our long-term outcomes multicenter study fill a gap and provide knowledge about the prevalence of emotional and physical disabilities among pediatric or adult survivors of burns suffered during childhood and evaluating the impact of advancements in burn care and rehabilitation on survivors' quality of life and reintegration.

Aims: Data collection for Specific Aim 1: NIDILRR Questionnaire which includes demographic data, VR-12(Veterans RAND), PHQ(Patient Health), CIQ(Community Integration), SL(Satisfaction with life Scale),5-D Itch Scale, etc. Specific Aim 2: Blood samples or buccal swabs. Genomic DNA will be isolated using a DNA extraction kit. The adrenergic and androgen receptors will be evaluated for clinically and functionally relevant SNP's. Specific Aim 3: Physical Activity Monitors will assess the daily activity levels of patients. Specific Aim 4: Fasting plasma glucose and fasting plasma insulin.

Role: Co-Principal Investigator
Contact: Dr. Kenneth Wood, 330 C Street SW, 2511B, Washington, DC 20201, (202) 275-7469
Overlap: None

#84080 Shriners Hospitals for Children (PI: Herndon) – renewed on 1/1/17
#84090 Shriners Hospitals for Children (PI: Herndon) – renewed on 1/1/17
#71000 Shriners Hospitals for Children (PI: Herndon) – renewed on 1/1/17 (prev #71008)
#80100 Shriners Hospitals for Children (PI: Herndon) – renewed on 1/1/17
#85310 Shriners Hospitals for Children (PI: Herndon) – ended 12/31/16
CON23000 Novartis (PI: Herndon) – ended 12/31/16
90DP0043-02-00 (PI: Herndon) ended 9/29/17
90DPBU0003-01-00 NIDILRR (PI: Herndon) renewed 9/30/17
CON25835 Gillson (PI: Herndon/Finnerty) – ended 3/9/17
W81XWH-09-2-0194 (PI: Wolf/Suman) – effort ended on 1/1/17
#71006, Shriners Hospitals for Children (PI: Suman) ended 12/31/16
W81 XWH-14-2-0160 (PI: Suman) – effort ended 1/1/17
W81XWH-14-2-0162 (PI: Finnerty) – effort ended 1/1/17
Gillson-Longenbaugh award (PI: Finnerty/Herndon) – new project as of 7/20/17
R01 GM122936-01 (PI: Finnerty) – effort ended 1/1/17
R01 HD049471 (PI: Suman) – effort ended 1/1/17
R01 DK112268 (PI: Kajimura) – new as of 9/20/16
W81-XWH-17-C-0018 (PI: Herndon) – new as of 6/1/17

#71000 (Herndon) 01/01/17-12/31/21 0.12 cal mths
Shriners Hospitals for Children
"Mechanisms of Improved Wound Healing & Protein Metabolism with Glucose Control"
Goal: To determine the effects of tightly regulating blood glucose levels with metformin in severely burned children.
Aims: 1) To determine how metformin affects whole-body and organ function post burn on a clinical level; 2) To determine the mechanisms whereby metformin exert their effects post-burn on a cellular level.
Role: Principal Investigator
Contact: Carole Miller, 815 Market Street, Galveston, TX 77550, 409-770-6728, cmiller@utmb.edu
Overlap: None

*****End Date Extended*****
#79141 (Herndon) 01/01/13-12/31/17 0.12 cal mths
Shriners Hospitals for Children
"Multi-Center Project: Safety and Efficacy of Propranolol in Severely Burned Children"
Goal: To test the safety and efficacy of propranolol in treating pediatric burn patients
Aims: We will determine the safety and efficacy of administration of propranolol for one year in severely burned children in a multi-center study involving the 4 Shrine burn hospitals. Propranolol will be evaluated in comparison to the current standard of care. 1) Determine the safety and efficacy of 4mg/kg/day propranolol for reducing heart rate and rate pressure product. 2) Determine the effect of propranolol on muscle function by measuring peak strength and endurance. 3) Determine the effect of propranolol on infections, sepsis, systemic inflammation, and scarring. 4) Determine the effect of propranolol on quality of life assessed by the ABA/Shriners outcomes indicators.
Role: Principal Investigator
Contact: Carol Miller, Shriners Hospitals for Children, 409-770-6628
Overlap: None

End Date Extended*

2P50 GM060338-16 (Herndon) 09/01/17-08/31/18 1.44 cal mths
National Institutes of Health
"Modulation of the Post-burn Catabolic Response by Modification of Androgen and Glucocorticoid Pathways"
1) To determine the extent to which corticosteroid/androgen pathway modulation with OX improves clinical outcomes, whole -body function, and psychosocial health after burns; 2) To determine the basic mechanisms underlying the ability of corticosteroid/androgen pathway modulation with OX to restore homeostatic muscle, fat, and glucose metabolism after burns; 3) To determine the mechanisms underlying the ability of corticosteroid/androgen modulation with OX to influence the inflammatory response and related processes of wound healing and infection resistance.
Project Title: Core A. Administrative Core
Goal: To identify pharmacological and non-pharmacological strategies to counter maladaptive responses to burns to improve patient recovery.
Aims: 1) To set the overall scientific direction of the P50 Burn Center and oversee the scientific progress of each Center component; 2) To provide financial management for projects, cores, and the overall Center; 3) To provide administrative support to the Human Subjects and Biostatistics cores and facilitate investigator access to core resources; 4) To disseminate P50 Center findings, promote Center research, and initiate Center communications/reporting.
Role: Co-Investigator
Contact: Scott D. Somers, PhD, Program Official, 45 Center Drive, Bethesda, MD 20814, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

End Date Extended*

2P50 GM060338-16 (Herndon) 09/01/17-08/31/18 0.96 cal mths
National Institutes of Health
"Modulation of the Post-burn Catabolic Response by Modification of Androgen and Glucocorticoid Pathways"
Project Title: Project 1. Clinical, Functional, and Biochemical Outcomes in Response to Androgen and Oxidative Stress Modulation
Goal: To identify pharmacological and non-pharmacological strategies to counter maladaptive responses to burns to improve patient recovery.
Aims: 1) To determine the effects of long-term OX administration on clinically relevant outcomes, as reflected by growth rate and growth arrest, length of hospital stay and psychosocial health; 2) To assess the effects of long-term OX on bone and muscle mass and their function, as reflected by strength and cardiopulmonary endurance; 3) To determine the effects of long-term OX on oxidative stress and the glucocorticoid response, as reflected by oxidant and antioxidant concentrations.
Role: Project Leader
Contact: Scott D. Somers, PhD, Program Official, 45 Center Drive, Bethesda, MD 20814, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

End Date Extended*

2P50 GM060338-16 (Herndon) 09/01/17-08/31/18 0.96 cal mths
National Institutes of Health
"Modulation of the Post-burn Catabolic Response by Modification of Androgen and Glucocorticoid

Pathways"
Project Title: Core C. Human Subjects Core
Goal: To identify pharmacological and non-pharmacological strategies to counter maladaptive responses to burns to improve patient recovery.
Aims: 1) To enroll patients, gather clinical data and measurements and oversee the acquisition, compilation, and dissemination of all clinical and biological data; 2) To collect, catalogue, and distribute patient samples; 3) To perform basic protein and genetic analyses.
Role: Core Director
Contact: Scott D. Somers, PhD, Program Official, 45 Center Drive, Bethesda, MD 20814, 301-594-3827, somerss@nigms.nih.gov
Overlap: None

End Date Extended*

2P50 GM060338-16 (Herndon) 09/01/17-08/31/18 0.24 cal mths
National Institutes of Health
"Modulation of the Post-burn Catabolic Response by Modification of Androgen and Glucocorticoid Pathways"
Project Title: Project 9. The Role of Androgen/Corticosteroid in Fat, Muscle and Glucose Metabolism of Burn Victims.
Goal: To identify pharmacological and non-pharmacological strategies to counter maladaptive responses to burns to improve patient recovery.
Aims: 1.1) To determine the impact of OX treatment on SM protein turnover in critical cellular compartments; 1.2) To determine the impact of OX treatment on SM contractile fiber composition and oxidative capacity; 1.3) To identify the key molecular pathways altered by OX treatment in SM of burn victims; 2) To determine the effect of OX treatment on fat distribution and AT lipid metabolism; 3) To determine the effect of OX treatment on glucose metabolism.
Role: Project Leader
Contact: Scott D. Somers, PhD, Program Official, 45 Center Drive, Bethesda, MD 20814, 301-594-3827, somerss@nigms.nih.gov

W81XWH-11-1-0835 (Herndon) 07/15/14-10/29/17 0.24 cal mths
American Burn Association
"(PI and Site Agreement) Protective Effects of Propranolol Following Severe Thermal Injury: A Safety and Efficacy Trial"
Goal: To determine safety parameters for the administration of propranolol to severely burned adults.
Aims: 1) To determine the dose at which propanolol will achieve reduction of cardiac rate pressure product during the acute post-injury period. 2) To evaluate the safety of propranolol administered to severely burned adult patients in the early post-injury period.
Role: Principal Investigator
Contact: Susan M. Browning, MPH, Deputy CEO and COO, 312-642-9260
Overlap: None

#79144 (Sheridan) 01/01/15-12/31/19 0.12 cal mths
Shriners Hospitals for Children
"Multi-Center Grant: System for Feedback of Patient Oriented Outcomes in Children with Burns"
Goal: To develop and test the effectiveness of a feeback system for patient reported outcomes in children with burns

Aims: 1) To establish and perform pilot tests of a "data through put system" on the basis of the BOQ instuments with subjects 11-18 years of age; 2) To conduct a randomized clinical trail at 4 SHC burn centers among clinical practices with and without the feedback of BOQ information and recommendations within each of the 4 sites

Role: Principal Investigator

Contact: SHC Boston: Martha Lyndon, RN, BS, 617-371-4808, mlyndon@shrinenet.org

Overlap: None

R01 GM056687-16 (Herndon) 05/01/15-04/30/18 1.80 cal mths

National Institutes of Health

"Mechanisms of fenofibrate alone or combined with propranolol in burned patients"

Goal: This long-term clinical trial will advance the understanding of burn-induced tissue-specific signaling pathways, alterations in clinical indices such as insulin resistance, body composition, and scarring, and may
improve clinical outcomes of burn patients, and by extension also improve these in other hypermetabolic and hypercatabolic states.

Aims: Aim 1: will characterize the effects of fenofibrate and propranolol on muscle protein metabolism, regional lipid metabolism, and insulin resistance, after severe burn. Aim 2a: will test the efficacy of these agents on wound closure, wound infection, graft rejection, and scarring (the modified Vancouver and Seattle scar scales). Aim 2b, will determine whether these agents alter wound protein turnover and healing rates by using stable isotope techniques. Aim 2c, will use fibroblasts isolated from skin and scar biopsies to study molecular signaling pathways related to wound healing and scar development. Aim 3: will test the hypothesis that the mechanistic results of SA1 and SA2 are highly associated with improvements in outcomes vital in the acute stage: inflammatory response as reflected by interleukin-6, as well as result in improvements in long term outcomes: lean body mass, resting energy expenditure, cardiac function and quality of life.

Role: Principal Investigator

Contact: Scott D. Somers, PhD, Program Official, 301-594-3827, somerss@nigms.nih.gov

Overlap: None

Gillson (Finnerty/Herndon) 07/20/17-07/19/18 0.12 cal mths

Gillson-Longenbaugh Foundation

"Investigation of the Use of Stem Cells"

Goal: Investigation of the use of stem cells (incl adipose derived [ASC] & other stem cells & the stromal vascular fraction [SVF]) and related proteins (Secretome) to promote burn wound healing and to reduce or ameliorate (hypertrophic) scar formation, including both porcine & human clinical trials, and investigation of secretome to identify proteins enhancing cell migration, proliferation, & fibrotic gene expression.

Aims: Same as goal

Role: Co-Principal Investigator

Contact: Lawrence I. Levy, 2121 Sage Road, Suite 120, Houston, TX 77056, llevy@thelevynet.com, (713) 668-3021

Overlap: None

W81XWH-15-1-0143 (Branski) 07/01/15-06/30/19 0.12 cal mths
Dept of Defense
"Growth Hormone Therapy for Muscle Regeneration in Severely Burned Patients"

Goal: To determine whether restoration of depleted GH levels post-burn will lead to prevention of lean body mass loss and bone mineral content, improve rehabilitation, and accelerate reintegration of severely burned patients.

Aims: To determine the effects of recombinant human growth hormone (rhGH) supplementation on body composition, such as lean body mass loss and bone mineral content, and to assess if rehabilitation and subsequent reintegration of severely burned patients into society can be accelerated.

Role: Co-Principal Investigator
Contact: Primary contact: Dr. Nicole Enman, Science Officer, CDMRP, Phone: (301) 619-7040, Email: nicole.m.enman.ctr@mail.mil
Overlap: None

UL1TR001439 (Tyler) 04/01/16-03/31/18 Institute 0.12 cal mths
for Translational Sciences
"Tumor Microenvironment and Cancer Immunotherapy Multidisciplinary Translational Team"
Goal: To support additional translational correlative studies that benefit from UTMB experts on the immunosuppressive tumor microenvironment, particularly vis-a-vis tumor-associated macrophages and cancer-associated fibroblasts.
Aims: 1) To identify early predictors of response to ipilimumab in the window of 6-8 weeks between the beginning of the checkpoint blockade immunotherapy and melphalan chemotherapy delivered by ILI.
Role: Co-Investigator
Contact: Liz Ruiz, 301 University Boulevard, Galveston, TX 77555-0264, 409-772-1920, ebruiz@utmb.edu
Overlap: None

R01 DK112268 (Kajimura) 09/20/16-06/30/19 0.48 cal mths
University of California at San Francisco
"Biological Roles and Developmental Pathway of Burn-Induced Beige Fat in Humans"
Goal: The current objective is to extend our understandings on the biological roles and developmental pathway of human beige adipocytes that are recruited by severe burn injury.
Aims: Aim 1: We will test the hypothesis that burn-induced beige fat functions as a “metabolic sink” for glucose, fatty acids, and BCAA, which contributes to the prevention of onset/progression of post-burn hyperglycemia. Aim 2: We will define cellular and molecular characteristics of burn-induced beige adipocytes.
Role: PI of Subcontract
Contact: Paul B. Guimbatan; Contracts and Grants Officer; Research Services Coordinator; UCSF Research Management Services; 533 Parnassus Avenue, Suite U350, San Francisco, CA 94143, Campus Box 0634
Tel: 415-987-1548; email: mark.guimbatan@ucsf.edu
Overlap: None

90DPBU0003-01-00 (Herndon) 09/30/17-09/29/22 0.24 cal mths
National Institute on Disability, Independent Living, and
"Effects of anabolic steroids and blockade of chronic catecholamine mediated stress on psychosocial,

growth, scar, and physiologic outcomes after massive burn injury"

Goal: Our long-term outcomes multicenter study fill a gap and provide knowledge about the prevalence of emotional and physical disabilities among pediatric or adult survivors of burns suffered during childhood and evaluating the impact of advancements in burn care and rehabilitation on survivors' quality of life and reintegration.

Aims: Data collection for Specific Aim 1: NIDILRR Questionnaire which includes demographic data, VR-12(Veterans RAND), PHQ(Patient Health), CIQ(Community Integration), SL(Satisfaction with life Scale),5-D Itch Scale, etc. Specific Aim 2: Blood samples or buccal swabs. Genomic DNA will be isolated using a DNA extraction kit. The adrenergic and androgen receptors will be evaluated for clinically and functionally relevant SNP's. Specific Aim 3: Physical Activity Monitors will assess the daily activity levels of patients. Specific Aim 4: Fasting plasma glucose and fasting plasma insulin.

Role: Principal Investigator

Contact Dr. Kenneth Wood, 330 C Street SW, 2511B, Washington, DC 20201, (202) 275-7469

Overlap: None

W81XWH-17-C-0018 (Herndon) 06/01/17-04/10/19 0.12 cal mths

CRD Research Corporation

"Burn Injury Assessment Tool with Morphable 3D Human Body Models"

Goal: To begin a clinical research trial utilizing the newly developed software with patients that have received burn injuries.

Aims: To begin a clinical research trial utilizing the newly developed software with patients that have received burn injuries.

Role: PI of Subcontract

Contact: Deb Phipps, Huntsville, AL 35806

Overlap: None

Lee, Jong
R01 GM112936-01 (PI: Finnerty) – added to project as of 1/1/17

2016-2018 ETEP (Lee) 05/01/16-06/30/18 0.60 cal mths
Texas Higher Education Coordinating Board
"Emergency and Trauma Care Education Partnership Program"

Goal: To provide salary and training support for fellows enrolled in the UTMB/Shriners Hospital Surgical Critical Care Fellowship program.

Aims: To provide salary and training support for fellows enrolled in the UTMB/Shriners Hospital Surgical Critical Care Fellowship program.

Role: Principal Investigator

Contact: Fu-An Lin, PhD, Program Director, Academic Quality and Workforce Division, 512-427-6211, fu-an.lin@thecb.state.tx.us

Overlap: None

*****End Date Extended*****
2P50 GM060338-16 (Herndon) 09/01/17-08/31/18 0.48 cal mths
National Institutes of Health
"Modulation of the Post-burn Catabolic Response by Modification of Androgen and Glucocorticoid Pathways"
Project Title: Core C. Human Subjects Core

Goal: To identify pharmacological and non-pharmacological strategies to counter maladaptive responses to burns to improve patient recovery.

Aims: 1) To enroll patients, gather clinical data and measurements and oversee the acquisition, compilation, and dissemination of all clinical and biological data; 2) To collect, catalogue, and distribute patient samples; 3) To perform basic protein and genetic analyses.

Role: Core Director

Contact: Scott D. Somers, PhD, Program Official, 45 Center Drive, Bethesda, MD 20814, 301-594-3827, somerss@nigms.nih.gov

Overlap: None

*****End Date Extended*****
2P50 GM060338-16 (Herndon) 09/01/17-08/31/18 0.12 cal mths
National Institutes of Health
"Modulation of the Post-burn Catabolic Response by Modification of Androgen and Glucocorticoid Pathways"
Project Title: Project 9. The Role of Androgen/Corticosteroid in Fat, Muscle and Glucose Metabolism of Burn Victims.

Goal: To identify pharmacological and non-pharmacological strategies to counter maladaptive responses to burns to improve patient recovery.

Aims: 1.1) To determine the impact of OX treatment on SM protein turnover in critical cellular compartments; 1.2) To determine the impact of OX treatment on SM contractile fiber composition and oxidative capacity; 1.3) To identify the key molecular pathways altered by OX treatment in SM of burn victims; 2) To determine the effect of OX treatment on fat distribution and AT lipid metabolism; 3) To determine the effect of OX treatment on glucose metabolism.

Role: Project Leader
Contact: Scott D. Somers, PhD, Program Official, 45 Center Drive, Bethesda, MD 20814, 301-594-3827, somerss@nigms.nih.gov

W81 XWH-14-2-0160 (Suman) 09/15/14-09/14/18 0.12 cal mths
Dept of Defense
"Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health and Physical Performance"

Goal: To obtain a successful, quantifiable exercise program (MP10) which can be a platform for future rehabilitation programs in burns or trauma.

Aims: 1) To characterize what is Standard of Care throughout hospital stay across the US. 2) To characterize outcomes in burn inpatients.

Role: Co-Investigator
Contact: Doug Medcalf, 301-619-2394, douglas.a.medcalf.civ@mail.mil

Overlap: This is the grant for which the progress report is being submitted.

W81XWH-15-1-0143 (Branski) 07/01/15-06/30/19 0.24 cal mths
Dept of Defense
"Growth Hormone Therapy for Muscle Regeneration in Severely Burned Patients"

Goal: To determine whether restoration of depleted GH levels post-burn will lead to prevention of lean body mass loss and bone mineral content, improve rehabilitation, and accelerate reintegration of severely burned patients.

Aims: To determine the effects of recombinant human growth hormone (rhGH) supplementation on body composition, such as lean body mass loss and bone mineral content, and to assess if rehabilitation and subsequent reintegration of severely burned patients into society can be accelerated.

Role: Co-Investigator
Contact: Primary contact: Dr. Nicole Enman, Science Officer, CDMRP, Phone: (301) 619-7040, Email: nicole.m.enman.ctr@mail.mil

Overlap: None

1 R01 GM112936-01 (Finnerty) 01/15/15-12/31/19 0.12 cal mths
National Institutes of Health
"Effects of Chronic Catecholamine Exposure on Post-burn Scarring"

Goal: Understanding the mechanisms underlying aberrant wound healing and scarring, and their reversal by propranolol, will lay the foundation to develop additional anti-scarring therapies for the severely burned.

Aims: Aim 1. Determine the effects of chronic catecholamine exposure and β-blockade on wound healing and hypertrophic scars. Aim 2. Quantitate the effects of β-blockade on scar composition. Aim 3. Determine the effects of β-blockade on β-AR expression, activity, and binding partners of dermal fibroblasts.

Role: Professor
Contact: Tseng, Hung H., 301-496-0810, tsengh@mail.nih.gov

Overlap: None

Early Mobility/Exercise Program (MP10) in the Burn Intensive Care Unit (ICU) Decreases Hospital Stay and Fatigue, and Improves Mental Health and Physical Performance

Log 13214039 Award # W81XWH-14-2-0160 Report period: 15-SEP-16 to 14-DEC-16

PI: Oscar E. Suman **Org: The Univ of Texas Medical Branch/Shriners Hospital-Galveston** **Award Amount:** $1,079,350.00

DMRDP

Study/Product Aim(s)

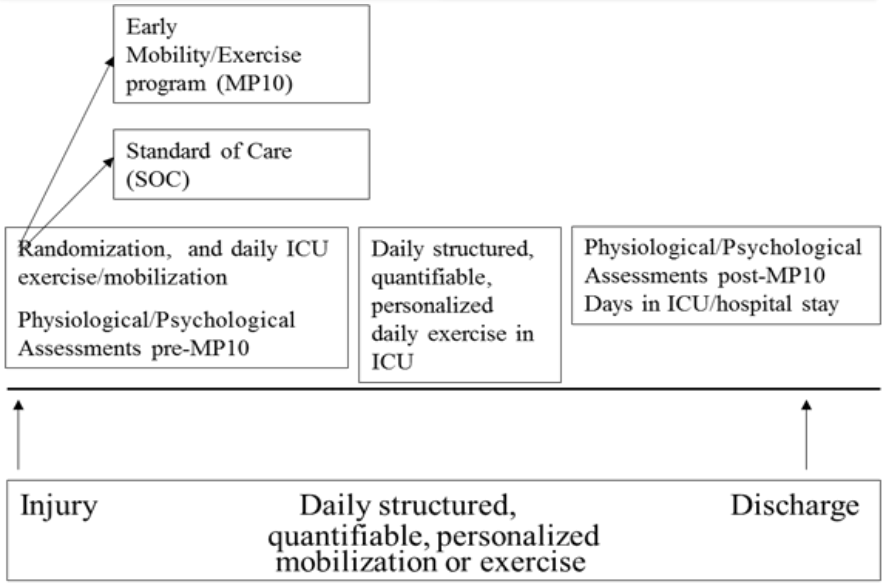
- **Objectives**: 1. decrease length of hospital stay 2. improve physiological and psychological outcomes
- **Aim 1**: Characterize SOC in the ICU in each of the 4 sites. **Aim 2**: Test the hypothesis that early exercise in the ICU will significantly improve outcomes compared to SOC.
- **Outcomes**: decreased ICU/hospital stay, improved lean mass, aerobic capacity/muscle endurance and fatigue scores.

Approach

Over 4 years, we will enroll 96 patients (24 per site; MP10 n=64 and SOC n=32) aged 18–60 years with ≥30% TBSA burns. Patients in MP10 will participate in a 10-minute leg-crank and a 10-minute arm crank ergometry session. Endpoints are lean body mass, cardiopulmonary and muscle endurance, length of BICU, ventilator and hospital stay, and Quality of Life.

Timeline and Cost

Activities CY	1	2	3	4
a. Construction and development of Survey to characterize SOC; b. submit for peer-reviewed publication				
Implement MP10+SOC vs SOC, obtain IRB, HRPO, register for clintrials,gov, enroll patients				
Submit manuscripts, present posters or oral presentations				
Estimated Budget ($K)	296,093	254,824	261,734	266,699



Goals/Milestones

CY1 Goal – IRB and HRPO approval for UTMB/SHC-GAL; UTSW; and UCD/SHC-NCA

Survey completion to characterize SOC completed by UTMB/SHC-GAL; UTSW; and UCD/SHC-NCA

CY2 Goals – MP10 enrolling at UTMB/SHC-GAL; UTSW; and UCD/SHC-NCA

Submission of abstract on Survey to ISBI

CY3 Goal – Continuation of MP10; Submission of manuscript (Aim 1)

CY4 Goal – Continuation of MP10

Analysis of data, submission of abstracts to ABA or other critical care meetings. Submission of manuscript. (Aim 2)

Comments/Challenges/Issues/Concerns

- Still waiting for IRB/HRPO approval from USAISR

Budget Expenditure to Date

Actual expenditures: 222,241.68

Projected expenditures: 616,350.50

Updated: DEC- 24-2016